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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,010	09/08/2004	Susumu Kuwabata	43888-332	8864

7590 10/05/2006

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Washington, DC 20005-3096

EXAMINER	
MARTIN, PAUL C	

ART UNIT	PAPER NUMBER
1657	

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/507,010	KUWABATA ET AL.	
	Examiner	Art Unit	
	Paul C. Martin	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04/03/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/22/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11 are pending in this application and were examined on their merits.

The Final Rejection mailed 05/10/06 has been withdrawn by the Examiner, and prosecution will resume in this current non-final action.

Applicant's amendment to obviate the objections to Claims 5 and 11 is accepted and the objections are withdrawn.

Applicant's amendments to Claims 1, 5, 6 and 11 and arguments therein are found sufficient and persuasive, and the rejection of Claims 1, 5, 6 and 11 under 35 USC § 112, second paragraph is withdrawn.

The rejection of Claims 1-4 and 8 under 35 USC § 102 (b) has been withdrawn as the Applicant's arguments were found to be persuasive regarding the current type used by the Ikeda *et al.* reference.

The rejection of Claims 1-11 under 35 USC § 103 (a) has been withdrawn as the Applicant's arguments were found to be persuasive regarding the current type used by the Ikeda *et al.* reference and the Applicant's amendment.

New Rejections (not necessitated by Applicant's amendment)

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikeda *et al.* (US 6,340,428 B1).

Ikeda *et al.* discloses a method for quantitating a substrate in a sample solution, comprising the steps of:

Supplying a sample solution containing substrate to an electrode system comprising a working electrode and counter electrode, and a third electrode to be used as an interfering substance detection electrode, under a reaction layer containing oxidoreductase and an electron mediator; applying an DC potential to the working electrode to cause a redox reaction of the electron mediator; measuring the electric signal produced by the redox reaction; and quantitating the amount of substrate based on the signal (Columns 12 and 13, Claim 5).

Ikeda *et al.* teaches a method further comprising a step of applying a DC potential between the working electrode and the counter electrode and measuring the current flowing between the working electrode and the counter electrode (Columns 12 and 13, Claim 5).

Ikeda *et al.* teaches wherein the oxidoreductase is glucose oxidase (Column 11, Line 41), and the electron mediator is a ferrocene derivative (Column 11, Line 46) and a sample measuring method wherein the effects of dissolved interfering substance ascorbic acid in a sample are removed (Column 5, Lines 25-32).

Ikeda *et al.* teaches that the working electrode and counter electrode are on the same plane, and are in positions opposed to each other across a space (Fig. 1).

Claims 1-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikeda *et al.* (US 6,340,428 B1) in view of Kuwabata *et al.* (2001).

The teachings of Ikeda *et al.* were discussed above.

Ikeda *et al.* does not teach wherein a central potential of the AC potential is within the range of –0.4 to +0.4 V relative to a redox potential of said electron mediator, and said central potential (Ecen) and the most negative potential in a potential region where the reaction of an interfering substance at the working electrode is diffusion-controlled (Emin) satisfy the following equation: Ecen > Emin –0.05 (V).

Ikeda *et al.* does not teach wherein a central potential of the AC potential being within the range of –0.1 to +0.1 V relative to a redox potential of said electron mediator, and said central potential and the most negative potential in a potential region where the reaction of an interfering substance at the working electrode is diffusion-controlled (Emin) satisfy the following equation: Ecen > Emin –0.05(V).

Ikeda *et al.* does not teach a method of quantitating a substrate in which the electric signal that is measured is impedance.

Kuwabata *et al.* teaches the step of applying an AC potential to the working electrode to cause a redox reaction of the electron mediator characterized by the central potential (0.5 V) of the AC potential being within the range of –0.4 to 0.4 V (0.18 V) relative to a redox potential of the electron mediator ferrocene carboxylic acid (0.32 V), and is a potential that is –0.05 relative to the most negative potential in a potential region where the reaction at the working electrode is diffusion controlled (Page 1, Lines 16-18 and Page 2, Line 20-25).

Kuwabata *et al.* teaches the step of applying an AC potential to the working electrode to cause a redox reaction of the electron mediator characterized by the central potential (0.5 V) of the AC potential being within the range of –0.1 to 0.1 V (0.09 V) relative to a redox potential of the electron mediator ferrocene carboxylic acid (0.23 V), and is a potential that is 0.05 relative to the most negative potential in a potential region where the reaction at the working electrode is diffusion controlled (Page 1, Lines 16-18 and Page 2, Line 20-25).

Kuwabata *et al.* teaches a method of quantitating a substrate in which the electric signal that is measured is impedance (Page 2, Lines 19-20).

Kuwabata *et al.* teaches a method of quantitating a substrate in which the oxidoreductase is glucose oxidase and the electron mediator is ferrocene carboxylic acid (Page 1, Lines 11-13).

Kuwabata *et al.* teaches that the use of AC measurement will allow the characterization of both the electron transfer process and the diffusion process of an electrochemical enzyme reaction (Pg. 2, Lines 1-10).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method for quantitating a substrate in a sample solution containing a dissolved interfering substance as taught by Ikeda *et al.* with the method of applying AC impedance measurements to the electrocatalytic reactions of glucose oxidase because this would allow one of ordinary skill in the art to detect and analyze both steps of the electrochemical enzyme reaction.

One of skill in the art would have recognized that the use of ferrocene carboxylic acid as described by Kuwabata *et al.* would have been an obvious variant or the ferrocene derivatives described by Ikeda *et al.* One of ordinary skill in the art would have been motivated to combine the two methods in order to more completely characterize the enzyme reaction steps of electron transfer and diffusion. There would have been a reasonable expectation of success in combining these two methods because both are drawn to the use of glucose oxidase and electron mediators as glucose sensors.

Claims 1-4, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikeda *et al.* (US 6,340,428 B1) in view of Ju *et al.* (1998).

The teachings of Ikeda *et al.* were discussed above.

Ikeda *et al.* does not teach a method wherein the working electrode is a rotating disk electrode or a microelectrode.

Ju *et al.* teaches a method of quantitating a glucose in which the working electrode is a rotating disk electrode (Page 541, Column 2, Lines 18-19) or micro-electrode (Page 541, Column 1, Lines 5-7) and the inherent advantages of using microelectrodes or rotating disk electrodes, such as being virtually free of fouling by interfering substance ascorbic acid and more rapid response time (Pg. 541, Column 2, Lines 10-20).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method for quantitating a substrate in a sample solution containing a dissolved interfering substance as taught by Ikeda *et al.* with the use of a rotating disk electrode or a micro-electrode as taught by Ju *et al.* because both types of electrodes were known in the art as being used in glucose biosensors using glucose oxidase. One of ordinary skill in the art at the time of the invention would have been motivated to combine the two methods because of the advantages taught by Ju *et al.* over conventional electrodes. There would have been a reasonable expectation of success in making this adaptation because both methods are drawn to the use of glucose oxidase biosensors detecting glucose in the presence of dissolved interfering factors.

Claims 1-4, 8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikeda *et al.* (US 6,340,428 B1) in view of Crumbliss *et al.* (1986) and Higgins (1987).

The teachings of Ikeda *et al.* were discussed above.

Ikeda *et al.* does not teach wherein the oxidoreductase is pyrroloquinone quinine dependent glucose dehydrogenase and the electron mediator is ruthenium hexacyanate.

Higgins *et al.* teaches the use of pyrroquinoline quinine dependent glucose dehydrogenase in a method of quantitating a substrate in a liquid mixture (Column 4, Line 16-18).

Crumbliss *et al.* teaches the use of hexacyanoruthenate as an electron mediator in a reaction to quantitate a substrate (Page 327, Line 10).

It would have been obvious to one of ordinary skill in the art to combine the method for quantitating a substrate in a sample solution containing a dissolved interfering substance using an oxidoreductase/electron mediator biosensor as taught by Ikeda *et al.* with the use of the oxidoreductase pyrroloquinone quinine dependent glucose dehydrogenase as taught by Higgins *et al.* and the electron mediator ruthenium hexacyanate as taught by Crumbliss *et al.* because one of ordinary skill in the art would have recognized them as functional equivalents to the oxidoreductases and electron mediators taught in the method of Ikeda *et al.* One of ordinary skill in the art would have been motivated to make these substitutions as a matter of optimizing the experimental conditions in order to combine the best reaction components. There would have been a reasonable expectation of success in making these substitutions because an oxidoreductase and electron mediator used in one method can be considered to be equivalent to an oxidoreductase and electron mediator used in another method.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one with ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence or evidence to the contrary.

No Claims are allowed.

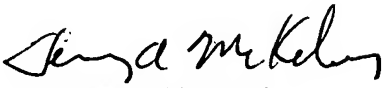
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1655

08/23/06



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